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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,630

06/27/2003

Zeina Tannous

MGH-036AUS

8743

22494

7590

06/13/2006

DALY, CROWLEY, MOFFORD & DURKEE, LLP  
SUITE 301A  
354A TURNPIKE STREET  
CANTON, MA 02021-2714

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,630	<b>Applicant(s)</b> TANNOUS ET AL.	
	<b>Examiner</b> Hong Sang	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **RE: Tannous**

1. Applicant's response filed on 5/5/2006 is acknowledged. Claims 1-11 are amended.
2. Claims 1-11 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Objections Withdrawn***

5. The objection to the drawings as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Fig. 5A and Fig. 5B. is withdrawn in view of applicants' amendment to the specification.

#### ***Rejections Withdrawn***

6. The rejection of claims 1 and 10 under 35 U.S.C. 102(b) as being anticipated by Richards-Kortum et al. (US Patent No. 6,187,289 B1, Date of Patent 2/13/2001, effective filing date 10/20/1998) is withdrawn in view of applicants' amendment to the claims.

***Response to Arguments***

7. The rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Richards-Kortum et al. (US Patent No. 6,187,289 B1, Date of Patent 2/13/2001, effective filing date 10/20/1998) in view of Yamamoto (US Patent No. 4,395,398), Prevendar (US Patent No. 6,652,840, effective filing date at least 2/8/2002) and Klaveness et al. (US Patent No. 6,159,445) and Rajadhyaksha et al. (J. Invest. Dermatol. 1999, 113: 293-303) is maintained.

The response states that Examiner has failed to explain why independent claim 1 and dependent claim 10 were rejected under 103(a) over Richards-Kortum in view of Yamamoto, Prevendar, Klaveness and Rajadhyaksha as indicated other than referring back to the 102(b) rejection. The response states that the applied art is not understood to disclose or suggest applying a predetermined contrasting solution including an AICI solution to an in-vivo defect area associated with the tumor for optically enhancing the at least one cell anomaly associated with the tumor. Yamamoto discloses various compounds including applying an aluminum chloride mixtures that may be applied to gums to stop the gums from bleeding. Prevendar discloses using a composition that includes aluminum chloride as a hemostatic agent to control gum bleeding. Klaveness disclosed particulate contrasting agents. Rajadhyaksha discloses a confocal scanning laser microscopy for examining human skin. None of the Yamamoto, Prevendar, Klaveness and Rajadhyaksha disclose or suggest applying the AICI solution to tumors much less using the AICI as a contrasting solution for optically enhancing the at least one cell anomaly associated with the tumor. Therefore, none of them disclose or

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suggest applying the predetermined contrasting solution including an AICI solution to an in-vivo defect area associated with the tumor for optically enhancing the at least one cell anomaly associated with the tumor. Moreover, there is no motivation to combine these references because Yamamoto and Prevendar are directed to controlling bleeding in the gums, and applicant's invention relates to observing tumors. Yamamoto and Prevendar make no reference to tumors or optically enhancing at least one cell anomaly associated with the tumor. Furthermore, Klaveness makes no mention of an AICI solution or offers any motivation for using the AICI solution as a contrasting solution. Rajadhyaksha does not disclose or suggest contrasting agents much less a predetermined contrasting agent comprising an AICI solution. Therefore, one of ordinary skill in the art would not have been motivated to combine these references.

The reason that claims 1 and 10 were included in the previous 103(a) rejection is that Richards-Kortum reference cited in the rejection anticipates these claims as set forth in 102(b) rejection (see previous office action page 5, 2<sup>nd</sup> paragraph).

Applicants' arguments have been carefully considered but are not found persuasive. The amendment to the claims cannot overcome the instant rejection. Richards-Kortum et al. teach a method of using acetic acid as a contrast agent for confocal imaging of cells *in vivo* comprising the steps of (a) applying acetic acid to a diagnostic tissue sample in sufficient concentration to induce an alteration of the index of refraction of nuclei in the cells; and (b) imaging the cells using a reflectance confocal imaging system (see claims 1 and 4). Richards-Kortum et al. teach that after the addition of acetic acid, images of tissue can be obtained which illustrate characteristic

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differences between normal and neoplastic tissue throughout the entire epithelial thickness (see column 4, lines 31-41). Because the instant claims recite the phrase "contrasting solution comprising an AlCl solution", the word "comprising" is open language and does not preclude other agents, such as acetic acid used in Richards-Kortum reference. Yamamoto teaches that an aqueous solution of aluminum chloride can be used as a hemostatic composition for local application to small hemorrhages in the dental field, for example, bleeding from gums which occurs during dental surgery (see column 1, lines 8-16 and 67-68). Prevendar teaches that an aqueous solution of aluminum chloride can also be used to stop bleeding and seal open small blood vessels while accelerating the healing process of skin (epithelial) tissues (see column 2, lines 29-31). Klaveness teaches the use of particulate materials as contrast agents in *in vivo* light imaging including confocal microscopy (see abstract and column 8, line 48). Klaveness teaches unlike all the light imaging dyes or contrast agents described in the state of the art that enhance contrast by changing the incident light absorption and/or fluorescence, the particulate materials enhance contrast by changing light scattering (see column 7, lines 49-65). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include AlCl solution in the contrast solution of Richards-Kortum et al. in view of the teachings of Yamamoto, Prevendar and Klaveness. One would have been motivated to include AlCl solution in the contrasting solution of Richards-Kortum et al. because AlCl solution provides two advantages as taught by Yamamoto, Prevendar and Klaveness. The first advantage of using AlCl solution is that aluminum solution can be used to stop bleeding during and/or after

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surgery. Because the method of Rajadhyaksha et al. involves excising a layer of tissue for ex-vivo imaging, one would be motivated to use AICI solution to stop tissue bleeding caused by excising the tissue. The second advantage of using AICI solution is that AICI when prepared in anhydrous alcohol forms fine particles that can change light scattering and enhance the contrast of image. Because of the reasons above, the rejection is still deemed proper and therefore is maintained.

### ***Conclusion***

8. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang  
Art Unit 1643  
June 1, 2006



**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**